



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,082	10/22/1999	ULRICH FEIGE	A-527	4189

21069 7590 10/28/2002
AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS, CA 91320-1799

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/428,082

Applicant(s)

FEIGE ET AL.

Examiner

Sheela J Huff

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002 and 13 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10 and 52 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1642

DETAILED ACTION

Response to Amendment

The amendment filed on 2/28/02 and 8/13/02 have been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-7, 10 and 52 are currently under consideration. Applicant should note that claim 7 has been rejoined with claims 1-6, 10 and 52.

Information Disclosure Statement

The IDS filed 2/28/02 and 6/7/02 have been considered-in-part. The reference were not found. The Examiner has pulled the US patents and a few foreign documents and considered them. However, the non-initialed documents on the Ids filed 2/28/02 and the three on the IDS filed 6/7/02 have not been considered. If applicant still wishes to have these considered, then applicant is requested to re-submit the references. A copy of the PTO-1449 filed 2/28/02 is enclosed.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1642

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 5-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bendele et al, WO 98/24477 or Collins et al WO 97/28828. Please note that Kohler has been removed from the rejection. Also claim 4 has been removed from this rejection. The reasons for this rejection are of record in paper no. 11, mailed 8/28/01.

Applicant argues that the references do not teach the fusion between the Fc and a peptide. Applicant should note that the rejected claims have no limitation of the size of the peptide claimed. Thus, the claim reads on proteins.

Claims 1-3 and 5-6 and 10 and 52 (as they read on SEQ ID No. 213) remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bendele et al, WO 98/24477 or Collins et al WO 97/28828 in view of Yanofsky et al US 5608035 and Brems et al WO 98/46257. Please note that Kohler has been removed from the rejection. Also claim 4 has been removed from this rejection. The reasons for this rejection are of record in paper no. 11, mailed 8/28/01.

Applicant's arguments have been addressed above.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

Claims 1-6, 10 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bendele et al, WO 98/24477 or Collins et al WO 97/28828 in view of Yanofsky et al US 5608035, Brems et al WO 98/46257 and Capon et al US 5336603.

Bendele et al and Collins et al both disclose a carboxy-terminus modified chimeric protein which is a fusion of IL-1ra and "all or part of the constant domain of the heavy or light chain of human immunoglobulin" and the immunoglobulin can be IgG1 (see paragraph bridging pages 11-12 of Bendele et al and pages 12-13 of Collins et al). The chimeric protein can be used in the treatment of inflammatory disorders. This reads on applicant's invention when c=0.

The only difference between the claimed invention and the references is that the references do not specifically make the suggested chimeric protein and that the claims

Art Unit: 1642

encompasses the use of a linker (ie c=1). Additional differences include the lack of mention of SEQ ID No. 213

Seq ID No. 11 and 256 (which are IL-1 antagonists) in Yanofsky et al read on SEQ ID No. 213 of the instant invention.

Brems et al discloses that it is well known in the art to increase the half-life or to incorporate functions as such as Fc receptor binding into therapeutic proteins (page 3, lines 12-15).

Capon et al disclose the use of small peptides linked to the constant region of immunoglobulins and the formation of more than one peptide in tandem (see col. 5, lines 60 to col. 6, line 15 and col. 7, lines 10-30).

Therefore, in view of Yanofsky et al and Brems et al, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to replace the IL-1ra portion of the chimeric peptide in Collins et al or Bendele et al with SEQ ID No 11 or 256, to increase the half-life of the peptide or to incorporate functions as such as Fc receptor binding into the peptide. The use of linkers to produce chimeric proteins is very well known in the art and therefore the use of a linker is within the purview of one skilled in the art. Furthermore, as shown by Capon et al peptides can readily be fused to the constant region, thus the use of either peptides or proteins attached to the Fc region is obvious.

Art Unit: 1642

Allowable Subject Matter

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on M,Th 5:30 am-2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sheela J Huff
Primary Examiner
Art Unit 1642

sjh
October 28, 2002